VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 12/11/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Norman Ward, M.D.
Cheryl Gibson, M.D.
Lynne Vezina, R.Ph.
Frank Landry, M.D.
Stuart Graves, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
David Calabrese, R.Ph., (MHP)
Nancy Miner, (MHP)
Stacey Baker, OVHA
Brenda O'Connor, R.Ph., (MHP)
Erin Reisfeld, M.D., OVHA
Judy Jamieson, OVHA

Guests:

Amy Finn, Merck
Andrea Hayes, Sanofi-Aventis
David Canepa, Schering Plough
Glenn E. Dooley, Sr, Sanofi-Aventis
Ilir Topalli, Biogen Idec
James Kokoszyna, Allergan
Joe Winalski, Biogen Idec
Jolie-Beth Bonue,TAP
Jonathon Mast, AstraZeneca
Keith White, Genentech
Laura Manna, Biogen Idec
Maribeth Klettke, Sanofi-Aventis
Mark Golick, Schering Plough
Mary Brown, AstraZeneca
Michael Brousseau, Alkermes
Paul Amato, GSK
Paul Fauikos, BIPI
Renee Hagerty, Takeda
Scott Mosher, GSK
Ward Bennett, J&J
Wendy Pollinger, Eli Lilly

Frank Landry, M.D, Acting Chair, called the meeting to order at 6:59 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The November 2007 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Green Mountain Care: To date, approximately 8,000 calls have been received inquiring about the new insurance plans being offered by OVHA. So far nearly 2200 people have been enrolled in Catamount Health and an additional 600 people are participating in the Employer Sponsored Insurance (ESI) premium assistance.

4. Medical Director Update: *Erin Reisfeld, M.D. – Medical Director, OVHA*

- Nothing to report.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Buprenorphine Communication to Prescribers :
  The letter sent out to prescribers who have prescribed Suboxone® and/or Subutex® in the past six months was presented.

Public Comment: No public comment.

Board Decision: None needed.

- Vivitrol® Communication to Prescribers :
  The communication sent to the five prescribers who have prescribed Vivitrol® was presented. This letter describes the change in the prior authorization process with requests going directly to the MedMetrics Clinical Call Center.

Public Comment: No public comment.

Board Decision: None needed.

- CellCept® /Myfortic® Communication to Prescribers:
  Presentation and discussion deferred until January meeting.

- OVHA Pharmacy Bulletin re Buprenorphine PA Process, Upcoming Diabetic Testing Supply PDL Changes and Brand/Generic PDL Switches for 01/01/08:
  Presentation and discussion deferred until January meeting.

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Symbicort® (budesonide/formoterol) Inhaler - Recommended for addition to the PDL in the category Pulmonary: Inhaled Glucocorticoids, Metered-Dose Inhalers (Combination Product). A quantity limit of 0.34 gm/day (1 inhaler/month) was recommended.

Public Comment: No public comment

Board Decision: The Board approved the MHP recommendations as described.

- Exelon® (rivastigmine) Transdermal Patch - Recommended for addition to the PDL as the first transdermal patch available for use in Alzheimer's disease. A quantity limit of one patch per day was recommended.

Public Comment: No Public Comment

Board Decision: The Board approved the MHP recommendations noted above.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP) (to present all topics in this category except as noted))*
(Public comment prior to Board action)

- Alzheimer's Medications: Cholinesterase Inhibitors/NMDA Receptor Antagonists:
It was recommended that Exelon® capsules be moved to preferred with a quantity limit of two capsules per day. A quantity limit of one tablet per day was recommended to be established for Aricept®. Criteria for approval of non-preferred agents would now include a documented side effect, allergy or treatment failure to both Aricept® and Exelon®.

Public Comment: No public comment.

Board Decision: The updated table, preferred agents, revised clinical criteria and quantity limits were unanimously accepted as presented.

- Anti-Coagulants:
It was recommended that Fragmin® injection be moved to preferred. The criteria for approval of Innohep® was recommended to include that the prescriber provide a clinically valid reason why one of Lovenox®, Fragmin® or Arixtra® cannot be used. The category was subdivided into oral agents, unfractionated heparin, low molecular weight heparins and selective factor XA inhibitors.

Public Comment: No public comment.

Board Decision: The updated table, preferred agents and revised criteria were unanimously accepted.

- Anti-Infectives: Cephalosporins:
It was recommended that in the 3rd generation subcategory that Cedax® suspension and capsules be moved to PA required. Other preferred products have a broader spectrum of activity at lower cost. Criteria for approval of Cedax® would include a documented side effect or treatment failure to both of the preferred products.

Public Comment: No public comment.

Board Decision: The updated table and revised criteria were unanimously accepted.

- Anti-Infectives: Genital Antivirals:
Deferred until January meeting.

- Anti-Infectives: Topical Antibiotics:
It was recommended that the cream formulation of Bactroban® be moved to PA required due to its increased cost compared to the ointment. Criteria for approval of Bactroban® cream would include a documented side effect, allergy, or treatment failure with mupirocin or Bactroban® ointment.

Public Comment: No public comment.

Board Decision: The updated table and newly established clinical criteria were unanimously accepted.

- Gastrointestinals: Proton Pump Inhibitors
  It was recommended that Prevacid® Solutabs be available without PA for children less than 12 years old (rather than the previously established ≤ 7 years old).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously approved.

- Growth Stimulating Agents:
  It was recommended that Tev-Tropin® move to PA required due to its lack of pen formulation. It was also recommended that Norditropin® be moved to preferred agent after clinical criteria are met to offer an additional preferred choice for prescribers. Criteria for approval of non-preferred products would be a documented side effect, allergy, or treatment failure to Norditropin® and Nutropin®.

Public Comment: No public comment.

Board Decision: The revised table and clinical criteria were accepted as presented.

- Lipotropics: Fibric Acid Derivatives:
  Additional products were listed in the PA required section of the table that had not been previously shown. It was recommended that Triglide® move from preferred to PA required. Clinical criteria for a non-preferred product would include a documented side effect, allergy or treatment failure to generic gemfibrozil and Tricor®. Existing users of Triglide® would be grandfathered.

Public Comment: No public comment.

Board Decision: The revised table and clinical criteria were unanimously accepted.

- Lipotropics: Statins: *David Calabrese, R.Ph, (MHP)*
  The following changes were recommended for the high potency statins : (1) Quantity limit of one tablet per day for generic simvastatin (2) Crestor® moves to preferred after clinical criteria are met (previous trial of generic simvastatin), existing users to be grandfathered and quantity limit of one tablet per day (3) Quantity limit of one tablet per day for Lipitor® and Zocor® (4) Started and stabilized will no longer be considered a valid criteria for approval of a non-preferred agent (5) Criteria for approval of non-preferred agents to be a documented side effect, allergy or treatment failure to BOTH generic simvastatin and Crestor®. The following changes were recommended for the other potency statins: (1) Lescol® and Lescol® XL move to PA required, existing users to be grandfathered and quantity limit of one tablet per day (2) Quantity limit for lovastatin to be one tablet per day for 10 mg and 20 mg strengths and two tablets per day for the 40 mg strength. (3) Quantity limit for provastatin to be one tablet per day (4) Quantity limit for Altoprev® to be one tablet per day (5) Quantity limit for Mevacor® to be one tablet per day for 10 mg and 20 mg strengths and two tablets per day for the 40 mg strength (6) Quantity limit for Pravacol® to be one tablet per day.

Public Comment: No public comment.

Board Decision: The revised table, step therapy and clinical criteria were accepted with the requested change that the quantity limit of 40 mg pravastatin and Pravachol® be increased to two tablets per day and that the 80 mg tablet be blocked with messaging to the pharmacy to use 40 mg tablets. This change was requested due to the considerable price difference between the 40 mg and 80 mg tablets.

- Lipotropics: Miscellaneous/Combinations: *David Calabrese, R.Ph, (MHP)*
  It was recommended that Vytorin® be moved to PA required, existing users to be grandfathered and a quantity limit of one tablet per day be instituted. The criteria for approval of Vytorin® recommended to be that the patient has had an inadequate response to BOTH generic simvastatin and Crestor®. Zetia® will be placed as preferred after clinical criteria are met (trial of simvastatin and Crestor® unless contraindicated) (see September minutes for more complete Zetia® discussion).

Public Comment: Mark Golick, Pharm.D., Schering Plough - Commented on unique drug combination in Vytorin® and the statin sparing effect of Vytorin®.

Board Decision: The revised table and clinical criteria were unanimously accepted.

- Multiple Sclerosis Self Administered Injectables:
  It was recommended that the category be renamed "self" injectables. The category was divided into subcategories of "interferons" and "other". It was recommended that Avonex® move to preferred status.

Public Comment: Laura Manna, Biogen Idec – Stated that she had no further comments as she agreed with the recommendations.

Board Decision: The revised table and preferred agents were unanimously accepted.

- Pulmonary: Beta-Adrenergic Agents:
  It was recommended that Foradil® move to preferred after criteria for LABA (long acting beta agonists) are met (evidence of controller medication in pharmacy claims system or a diagnosis of COPD).

Public Comment: No public comment.

Board Decision: The revised table and preferred agents were unanimously accepted.

8. New Drug Classes:

- No new drug classes were proposed.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Mental Health Drug Use in Children 0 -17 years
  A high level summary of mental health medication utilization in children for the six month time period 04/01/07 through 09/30/07 was presented. Three age groups were examined: 0 through 6 years, 7 through 12 years and 13 through 17 years old. Claims were reviewed for prescriptions for antidepressants, antipsychotics and ADHD medications (stimulants and non-stimulants). Excluded from the review were anticonvulsants, anxiolytics and sedative/hypnotics. The percentage of Medicaid beneficiaries in each age group receiving one medication, two medications or three or more medications was calculated.

Public Comment: No public comment.

Board Decision: The Board requested that national comparative data be obtained from other states for their Medicaid recipients and possibly commercially insurers as well. Estimates of disease prevalence

were also requested. The Board also requested that the data be subdivided by antidepressants, antipsychotics and ADHD medications.

10. Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. A variety of products released on the market are not in a drug class that is currently managed or are not specifically addressed in the PDL. As approved by the DUR Board, drug products that appear to be illogical combinations, kits containing non-drug items or very expensive dosage forms where inexpensive alternatives exist are temporarily blocked and brought to the DUR Board on a periodic basis for approval of permanent block or a decision to unblock. The presented table highlights drug products blocked from drug files dated 10/25/07 – 11/21/07. DUR Board members were asked to comment if they felt that a drug product should not be blocked.

Public Comment: No public comment.

Board Decision: The Board determined that for future meetings each blocked product would not need to be individually discussed and that this topic could become a consent agenda topic.

11. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Erythropoiesis Stimulating Agents: Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) – hemoglobin targets The FDA notified healthcare professionals of revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs) which treat certain types of anemia. These new statements address the risks that the drugs Aranesp®, Epogen®, and Procrit® pose to patients with cancer and patients with chronic kidney failure and recommend target hemoglobin levels. It was recommended that no changes be made to our PDL or clinical criteria and that the alert be posted to the OVHA pharmacy website.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations and recommended that a letter describing the concerns be sent to all prescribers of ESAs who have prescribed in the most recent 6 months.

- Avandia® (rosiglitazone maleate) Tablets – potential increased risk of myocardial ischemia: The FDA informed healthcare professionals of new information added to the existing boxed warning in Avandia®'s prescribing information about potential increased risk for heart attacks. The new information refers to a meta-analysis of 42 clinical studies, most of which compared Avandia® to

placebo, that showed Avandia® to be associated with an increased risk of myocardial ischemic events such as angina or myocardial infarction. At this time, FDA has concluded that there isn't enough evidence to indicate that the risks of heart attacks or death are different between Avandia® and some other oral type 2 diabetes treatments. No changes to our PDL or clinical criteria are recommended at this time but the alert should be posted to the OVHA pharmacy web site.

Public Comment: Paul Amato ,Pharm.D., GSK – Commented that the data at this point in time is inconclusive and that the FDA approved labeling reflects this.

Board Decision: The Board approved all MHP recommendations.

- Chantix® (Varenicline) – suicidal thoughts, aggressive and erratic behavior : The FDA informed healthcare professionals of reports of suicidal thoughts and aggressive and erratic behavior in patients who have taken Chantix®, a smoking cessation product. There are also reports of patients experiencing drowsiness that affected their ability to drive or operate machinery. The FDA is currently reviewing these cases, along with other recent reports. The role of Chantix® in these cases is not clear. The recommendation is that no action is required on the part of the DUR Board in response to this communication. The communication will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

- Myfortic® (mycophenolic acid) Delayed-Release Tablets – use in pregnancy: Novartis and the FDA informed healthcare professionals and patients that use of Myfortic® Delayed- Release Tablets during pregnancy is associated with increased risks of pregnancy loss and congenital malformations. The pregnancy category for Myfortic® has been changed to Category D. The recommendation is that a patient specific mailing be sent to prescribers and that this mailing can be combined with the planned CellCept® mailing advising prescribers to counsel patients around the need for contraceptive use. The alert will be posted on the OVHA pharmacy web site.

Public Comment: No public comment.

Board Decision: The Board approved all MHP recommendations.

13. Adjourn: Meeting adjourned at 8:55 p.m.

Next DUR Board Meeting
Tuesday, January 15, 2008 **PLEASE NOTE DATE**
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.